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Subject: Inside EPA: Texas Weakens EtO Risk Value, Bolstering EPA Bid To Curb Air Toxics Rules

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Inside EPA:

Texas Weakens EtO Risk Value, Bolstering EPA Bid To Curb Air Toxics Rules

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Despite opposition from local officials, Texas has adopted a weaker risk value for ethylene oxide (EtO), a carcinogenic gas used to sterilize medical equipment, than the value EPA adopted in 2016, a move that could bolster imminent efforts by the federal agency to use the state's weaker values when crafting two pending air toxics rules.

Such weaker limits could help ease regulation of sterilization and other emitting facilities, as they seek to ramp up their work to address the coronavirus.

But any effort by EPA to use weaker risk values in its pending rules -- including a final measure revising air toxics limits for miscellaneous organic chemical facilities, which the agency submitted for White House review late last week -- will almost certainly draw a stiff challenge from states, environmentalists and others, who have strongly opposed EPA suggestions it will adopt such values.

Despite opposition from local officials, Texas Commission on Environmental Quality (TCEQ) May 15 finalized its risk evaluation of EtO, -- a substance used as an intermediate to make other chemical products like detergent, antifreeze and polyester, and to sterilize medical equipment and foods -- finalizing cancer risk estimates that are marginally stricter from those in a 2019 draft version.

TCEQ set an inhalation cancer risk estimate, known as a unit risk factor (URF), of 4.1x10-6 per parts per billion (ppb) or 2.3x10-6 per micrograms per cubic meter, or ug/m3, and a "chronic health-based effects screening level for nonthreshold dose response cancer effect" of 2.4 ppb or 4.3 ug/m3.

The state's risk values stand in contrast to EPA's 2016 assessment conducted by the agency's Integrated Risk Information System (IRIS) program, which found EtO to be 30 times more potent at causing cancer than IRIS' previous assessment and affirmed long-suspected claims that the chemical causes breast and lymph cancers.

EPA set a URF of 9.1x10-3 per ppb, which corresponds to a 1 in 100,000 excess cancer risk air concentration of 0.001 ppb. This cancer potency estimate is based on human epidemiology data of incidence of both lymphoid cancers and breast cancer.

One key difference in the agencies' risk values is that TCEQ does not use the breast cancer data for its risk calculations, though this was an omission which environmentalists had criticized in TCEQ's draft assessment. TCEQ, however, says in its final assessment that it "determined that the weight of evidence suggests a potential association between EtO and human lymphohematopoietic tumors but does not suggest an association with human breast cancer."

TCEQ's bases its conclusion on the breast cancer evidence on "weak primary epidemiological evidence for EtO-induced breast cancer," as well as recent meta-analyses evaluating the strength of

the overall weight of evidence for EtO-induced breast cancer that the commission says showed a lack of association between EtO and breast cancer.
In an appendix, TCEQ also says that it used a different dose-response model than IRIS, which used a more conservative supralinear dose-response model that assumes no safe level of exposure.
"USEPA ultimately chose to model EtO-induced lymphoid cancer, the key cancer endpoint used by the TCEQ, with a linear two-piece spline model. The linear two-piece spline model used by USEPA may be characterized as an overall supra-linear dose-response model that has a steep slope in the low-dose region with a "knot" as the point of an abrupt transition to the upper spline with a markedly reduced slope."
EPA's modeling choice was the subject of much debate among its peer reviewers, and a major focus of the two peer reviews the assessment underwent. Ultimately, two subsequent drafts of the assessment were reviewed in 2007 and 2014, resulting in EPA's final 2016 assessment.

IRIS Value

But a departure from EPA's IRIS value would mark a significant retreat for the agency. The program's risk levels underpin findings in its 2018 National Air Toxics Assessment (NATA), which found elevated health risks from EtO at facilities around the country and prompted intense local controversies, leading to the closure of sterilization facilities in Illinois and Georgia.
In addition, EPA's Office of the Inspector General (OIG) issued a management alert to the agency finding an "urgent" need to bolster outreach to communities subject to EtO air emissions. OIG warned that while EPA has identified 25 EtO-emitting facilities as high-priority because of their health risks, it has only met with residents near nine of those sites. But Administrator Andrew Wheeler called on the OIG to withdraw the document and teed up a formal dispute-resolution process.
Despite such local concerns, the Trump EPA has invited comment on whether the 2016 IRIS risk values are too stringent, as the chemical industry believes, and whether it should continue to use them in its regulations.
Should EPA depart from the IRIS value in its rules, it could require much more lenient emissions controls for those industries and set a broader precedent undercutting the agency's use of its IRIS values.
But environmentalists have warned that they will challenge any air toxics rules that depart from IRIS values, charging that TCEQ's risks values underestimate cancer risk by three orders magnitude, exclude analyses on breast cancer studies and early life exposures, and violate legal requirements that the agency use "best available science."
Two pending EPA rules could use the TCEQ risk values.
The first would restrict EtO emissions from the Miscellaneous Organic Chemical Manufacturing (MON) sector by up to 93 percent as part of the agency's strategy to curb EtO.
EPA based the proposed MON rule on its 2016 risk value estimated by its Integrated Risk Information System (IRIS) program.
But is also sought to address potential industry concern over its use of the IRIS values by increasing the acceptable risks the rule would address. While the agency noted that it generally uses a presumptive limit on maximum individual lifetime cancer risk of about 1 in 10 thousand or 100-in-1 million, in this case, it was willing to accept risks 200-300-in-1-million due in part to "risk estimation uncertainty."
EPA's air office also asked its research office last year to better explain why the IRIS assessment uses the cancer risk model that it does, resulting in a sensitivity analysis document outlining the pros and cons of various modeling choices.
The document outlines each alternative model and explains why the IRIS assessment did not choose the alternatives, usually due to the chosen model fitting better or based on recommendations from EPA science advisors. The memo adds that some of the discarded alternative models would have provided even stricter cancer risk estimates, though from the included chart, it appears most of the alternatives would have been less stringent.
EPA May 15 sent a draft final version of the MON rule to the White House Office of Management and Budget (OMB) for review, according to OMB's website.

The second EPA rule that could use TCEQ's value is an advanced notice of proposed rulemaking (ANPRM) that EPA issued last December that sought comment on possible ways to reduce EtO emissions from sterilization and fumigation facilities, a large source of all EtO emissions.

"The ANPRM will not impose any requirements on the regulated community; rather, it offers the public the opportunity to comment on specific topics for the agency to consider in developing a potential future proposed rule," EPA said.

But the ANPRM sparked a clash between medical device makers and Democratic state attorneys general over the agency's estimate of EtO risks and the potential for stricter emission control mandates.